

REMARKS

This Amendment is responsive to the final Office Action dated September 9, 2008, is submitted with a Request for Continued Examination, and constitutes a sufficient submission under 37 CFR § 1.114 for the Request for Continued Examination. Applicant has amended claims 19 and 37-54 and added claim 55. Claims 19-55 are pending.

Claim Rejections Under 35 U.S.C. §§ 102 and 103

In the Final Office Action, the Examiner rejected claims 19-23, 32-41, 50-54 under 35 U.S.C. § 102(b) as anticipated by Snell (US 5,716,382), or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Snell. The Examiner also rejected claims 19-54 under 35 U.S.C. § 103(a) as being unpatentable over Kroll et al. (US 7,123,961) in view of Snell. Applicant respectfully traverses these rejections to the extent such rejection may be considered applicable to the claims as amended. Snell not disclose each and every feature of the inventions defined by the amended claims, as required by 35 U.S.C. 102(b), and neither Snell, nor Kroll in view of Snell, provides any teaching that would have rendered inclusion of the undisclosed features obvious to a person of ordinary skill in the art, as required by 35 U.S.C. 103(a).

Response to Arguments

In the Response to Arguments section of the Final Office Action, the Examiner argued that Applicant's arguments in the previous Response relied on recitations of intended use in the claims, and therefore were not persuasive. The Examiner suggested that Applicant's arguments might be more compelling if, for example, the claims were amended to more positively recite the decision tree. Applicant appreciates the Examiner's guidance.

Applicant does not agree with the Examiner's characterization of the claims as previously presented as reciting intended use. Nevertheless, in the interest of advancing the prosecution of this application, Applicant has amended independent claims 19 and 37 to positively recite algorithmic instructions that define a decision tree, the decision tree comprising a plurality of nodes and branches and defining a hierarchy of possible parameter configurations for a neurostimulator to guide in the selection of parameter configurations, wherein each node defines an alternative parameter configuration from each of the other nodes and each branch links one of the nodes to another of the nodes. Applicant believes that these amendments to the independent

claims overcome the Examiner's argument regarding intended use. For at least the reasons stated in Applicant's previous Response, all claims are patentable over Snell, as well as Kroll in view of Snell.

Snell

Snell describes a decision support system for use by physicians in optimizing the parameters of an implantable cardiac device. The system is comprised of a rule engine unit, a set of rules, patient and device databases, and interfaces for interacting with the operator.¹ According to Snell, the operator engages with the system in a question and answer session, from which the system learns aspects of the patient's condition.² The answers provided by the operator are gathered from telemetric readings or from a patient/device database.³ Based on that information, the system recommends an appropriate operating configuration for the implantable device, or provides a list of recommendations from which the physician can choose.⁴

In contrast to Snell, claim 19 recites a computer-readable medium comprising algorithmic instructions that define a decision tree that comprises a plurality of nodes and branches and defines a hierarchy of possible parameter configurations, wherein each node defines an alternative parameter configuration from each of the other nodes, and each branch links one of the nodes to another of the nodes, and instructions to cause a processor to select a first parameter configuration for the neurostimulator, receive an indication of observed efficacy of the first parameter configuration, select a branch of the decision tree based on the indication of observed efficacy and a position of the first parameter configuration within the decision tree, and select a second parameter configuration for the neurostimulator based on the selected branch of the decision tree. Such features may, for example, permit an operator to refine an initial configuration, using the indications of the efficacy of the initial configuration, to a different configuration based on the appropriate branch of the decision tree. The Snell reference discloses neither the use of indications of observed efficacy of one (e.g., a current) parameter configuration to select a next parameter configuration, nor the use of a decision tree that defines a hierarchy of

¹ Snell at col. 3, lines 35-49.

² Snell at col. 3, lines 41-43.

³ Snell at col. 7, line 17.

⁴ Snell at col. 3, lines 44-48.

possible parameter configurations, nor the selection of a different parameter configuration on the basis of such indications and the present position within the decision tree.

The Examiner argued that FIGS. 4 and 5 of Snell disclose the use of observations of efficacy as a result of pacing. However, the examples cited by the Examiner relate to the patient's underlying condition and not to the effects of a particular (e.g., the current) pacing mode. In particular, the Examiner cited blocks 2, 3, 5, and 6 of FIG. 5. Block 2 asks the operator whether the patient's need for a pacemaker will be infrequent,⁵ while Block 3 asks whether pacing is needed as a result of neuroregulatory abnormality.⁶ These two questions relate to the patient's underlying condition;⁷ they are not answered by observing the effects of pacing, much less pacing in a current mode. Block 5 asks whether there is evidence of atrial fibrillation,⁸ and block 6 asks if ventricular rate increases with physiological stimulation.⁹ These two questions are also answered on the basis of the patient's underlying condition and not by observing the effects of pacing, much less pacing in a current mode.¹⁰

In the Snell system, the selection of a next parameter configuration is not the result of observations of the efficacy of pacing in a previous or current parameter configuration. Rather, the operator inputs information based on clinical observation of conditions unrelated to pacing. Snell therefore cannot anticipate the requirement of claim 19 of instructions to cause a processor to "receive an indication of observed efficacy of the first parameter configuration."

The Examiner stated that, in the Snell system, as a "result of its efficacy and the location of the first parameter configuration [, the device] selects a second parameter configuration." The Applicant has already shown that efficacy is not a component of the Snell system. In addition, the Snell system does not select subsequent parameter configurations based on the location of the position of the current configuration within a decision tree composed of a hierarchy of configurations. To the contrary, the various parameter recommendations in Snell, as illustrated in FIGS. 5, 6, and 7, are all *leaves* of the decision tree. That is, once a recommendation is reached through use of the decision tree, there are no further branches of decisions to take and the

⁵ Snell, FIG. 5.

⁶ *Id.*

⁷ Snell at col. 10, lines 40-51.

⁸ *Id.*

⁹ *Id.*

¹⁰ Snell at col. 11, lines 50-61.

tree traversal process is complete. Snell refers to these leaves/configurations as “tips” of the branches of the tree.¹¹ There are “62 such tips corresponding to 62 different recommendations for the adjustable pacing parameter.”¹² Because the configurations in Snell are the end result of the decision-making process, that reference cannot anticipate or make obvious the limitation of claim 19 that requires “select[ing] a branch of the decision tree based on the indication of observed efficacy and a position of the first parameter configuration within the decision tree.”

Kroll in View of Snell

Kroll fails to disclose or suggest a computer-readable medium comprising algorithmic instructions that define a decision tree that comprises a plurality of nodes and branches and defines a hierarchy of possible parameter configurations, wherein each node defines an alternative parameter configuration from each of the other nodes, and each branch links one of the nodes to another of the nodes, and instructions to cause a processor to select a first parameter configuration for the neurostimulator, receive an indication of observed efficacy of the first parameter configuration, select a branch of the decision tree based on the indication of observed efficacy and a position of the first parameter configuration within the decision tree, and select a second parameter configuration for the neurostimulator based on the selected branch of the decision tree, as recited in Applicant’s independent claim 19. The Examiner correctly noted that the present application differs from Kroll, at a minimum, in that it “recite[s] a hierarchy...of electrode configurations to form a decision tree to determine the optimum settings.”

However, the Applicant disagrees with the Examiner’s statement that to “have used such a well known method for selecting configurations in a known manner would have been obvious in view of Snell.” As already argued above, Snell does not disclose or suggest the use of a decision tree defined by a hierarchy of possible parameter configurations. The configurations in Snell are found only at the leaves of the decision tree. Once they are reached, the tree-traversal process is complete. In contrast to Applicant’s claim 19, therefore, the configuration in Snell is not used in conjunction with indications of observed efficacy in order to select the next parameter configuration by traversing the tree. Consequently, Snell does not cure the deficiencies of Kroll.

¹¹ Snell at col. 9, line 9.

¹² Snell at col. 9, lines 10-12.

While the above arguments were made with respect to claim 19, Applicant's independent claim 37 sets forth substantially similar limitations as that of claim 19. As a result, independent claim 37 benefits from the above arguments made with respect to claim 19, and Applicant requests prompt withdrawal of its rejection for similar reasons. Additionally, those claims 19-54 that depend on independent claims 19 and 37 also benefit from the above arguments made with respect to claim 19, and Applicant also requests withdrawal of the rejection set forth against these dependent claims.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 19-54 under 35 U.S.C. §§ 102(b) and 103(a). Withdrawal of these rejections is requested.

New Claim:

Applicant has added claim 55 to the pending application. The applied references fail to disclose or suggest the inventions defined by Applicant's new claim 55, and provide no teaching that would have suggested a rational reason for modification to arrive at the claimed inventions. No new matter has been added by the new claim.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims.

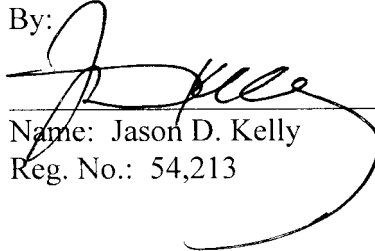
In view of the clear distinctions identified above between the current claims and the applied prior art, Applicant reserves further comment at this time regarding any other features of the independent or dependent claims. However, Applicant does not necessarily admit or acquiesce in any of the rejections or the Examiner's interpretations of the applied references. Applicant reserves the right to present additional arguments with respect to any of the independent or dependent claims.

Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

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